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[PCD 19: Cosmetics]

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IS : 6334 - 1987

Indian Standard
SPECIFICATION FOR
BUTYL *p*-HYDROXYBENZOATE FOR
COSMETIC INDUSTRY
(Second Revision)

UDC 547.587.12' 264 : 665.58

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

December 1987

Indian Standard
SPECIFICATION FOR
**BUTYL *p*-HYDROXYBENZOATE FOR
COSMETIC INDUSTRY**
(Second Revision)

Cosmetics Sectional Committee, PCDC 19

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(Continued on page 14)

Indian Standard

SPECIFICATION FOR
BUTYL *p*-HYDROXYBENZOATE FOR
COSMETIC INDUSTRY

(Second Revision)

0. FOREWORD

0.1 This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards on 8 June 1987, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

0.2 Butyl *p*-hydroxybenzoate is used as a preservative in the cosmetic industry; it prevents the growth of microorganisms.

0.3 This standard was first published in 1971 and subsequently revised in 1980. In this second revision, method of 'Assay' has been revised and test for sulphate has been modified to align the test methods with those given in the Pharmacopoeia of India 1985 (I. P. 1985). The requirement of pH has been deleted and replaced with the test reaction in line with I. P. Due to strong reservations regarding the use of potassium cyanide in a cosmetic testing laboratory in this revision, potassium cyanide method for test of heavy metals has been replaced by hydrogen sulphide method.

0.4 In the preparation of this standard, assistance has been obtained from the Cosmetic, Toiletry and Fragrance Association (CTFA) Inc., Specification for butyl paraben (Formerly TGA Spec No. 68), New York, 1971.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2 - 1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Rules for rounding off numerical values (revised).

1. SCOPE

1.1 This standard prescribes the requirements, and the methods of sampling and test for butyl *p*-hydroxybenzoate for cosmetic industry.

2. REQUIREMENTS

2.1 Description — The material shall be in the form of white or off-white, non-hygroscopic powder. The material is sparingly soluble in water (1 part in 5 000 parts) and freely soluble in ethyl alcohol.

2.2 The material shall comply with the requirements given in Table 1, when tested according to methods given in Appendix A. Reference to the relevant clauses of Appendix A is given in col 4 of the table.

TABLE 1 REQUIREMENTS FOR BUTYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

SL No.	CHARACTERISTIC	REQUIREMENT	METHOD OF TEST (REF TO CL NO. IN APPENDIX A)
(1)	(2)	(3)	(4)
i)	Melting range, °C	68 to 71	A-2
ii)	Heavy metals (as Pb), parts per million, <i>Max</i>	5	A-3
iii)	Arsenic (as As ₂ O ₃), parts per million, <i>Max</i>	1	A-4
iv)	Assay, percent by mass, <i>Min</i>	99.0	A-5
v)	Sulphated ash, percent by mass, <i>Max</i>	0.1	A-6
vi)	Chlorides	To pass the test	A-7
vii)	Sulphates	To pass the test	A-8
viii)	Reaction	To pass the test	A-9

3. PACKING AND MARKING

3.1 Packing — The commonly used size and material of construction of containers is 5 kg gusseted polythene bag which is further packed in 5-ply corrugated box of grammage 5 × 100 gsm or shall be subject to agreement between the purchaser and the supplier.

3.2 Marking — Each container shall be marked legibly and indelibly with the following information:

- a) Name and mass of the material in the containers;
- b) Manufacturer's name and recognized trade-mark, if any;
- c) Batch number, in code or otherwise, to enable the lot of manufacturer to be traced back from records; and
- d) Date of manufacture.

3.2.1 The containers may also be marked with the Standard Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

4. SAMPLING

4.1 The method for preparing representative test samples of the material and the criteria for conformity shall be as prescribed in Appendix B.

A P P E N D I X A

(Clause 2.2)

METHODS OF TEST FOR BUTYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

A-1. QUALITY OF REAGENTS

A-1.1 Unless specified otherwise, pure chemicals and distilled water (*see* IS : 1070 - 1977*) shall be used in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

*Specification for water for general laboratory use (*second revision*).

A-2. DETERMINATION OF MELTING RANGE

A-2.1 Apparatus

A-2.1.1 Oil-Bath — consisting of liquid paraffin in a glass container.

A-2.1.2 Heat Source — electrical or open flame, capable of being controlled to a desired rate of heating.

A-2.1.3 Capillary Tubes — of glass, 10 cm long and 0·8 to 1·3 mm in internal diameter.

A-2.1.4 Thermometer

A-2.2 Procedure

A-2.2.1 Reduce the sample to a fine powder. Fill in a capillary tube, which is sealed at one end, sufficient quantity of dry powder to form a column 2·5 to 3·5 mm in height, when packed down as closely as possible.

A-2.2.2 Heat the bath until a temperature approximately 30°C below the expected melting range is reached. Attach capillary tube containing the powdered sample to the thermometer by wetting both with a drop of liquid paraffin and adjust its height so that the material in the capillary is in level with the thermometer bulb. Return the thermometer to the bath and continue heating with constant stirring to raise the temperature at a rate of approximately 3°C per minute until a temperature 3°C below the expected melting range is attained. Then carefully regulate the rate to about 1 to 2°C per minute until the sample is completely melted.

A-2.2.3 The temperature at which the column sample is observed to collapse definitely against the side of the tube at any point shall be taken at the beginning of the melting and the temperature at which the sample becomes liquid throughout shall be taken at the end of melting.

A-2.2.4 Both the temperatures noted shall fall within the specified melting range.

A-3. TEST FOR HEAVY METALS

A 3.0 Outline of the Method — The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

A-3.1 Apparatus

A-3.1.1 Nessler Cylinder — 50-ml capacity.

A-3.2 Reagents

A-3.2.1 Concentrated Hydrochloric Acid — See IS : 265 - 1976*.

A-3.2.2 Concentrated Nitric Acid — See IS : 264 - 1976†.

A-3.2.3 Dilute Acetic Acid — 6 percent acetic acid (60 ml diluted to 1 000 ml with water).

A-3.2.4 Hydrogen Sulphide Solution — saturated.

A-3.2.5 Standard Lead Solution — Dissolve 1·600 g of lead nitrate in water and make up the solution to 1 000 ml. Pipette out 10 ml of the solution and dilute again to 1 000 ml with water. One millilitre of this solution contains 0·01 mg of lead (as Pb).

A-3.3 Procedure — Ignite 4·000 g of the material in a silica dish until completely ashed. To the residue, add 1 ml of hydrochloric acid and 0·5 ml nitric acid and evaporate to dryness on steam bath. Dissolve the residue in 5 ml hot water and 1 ml dilute acetic acid, and transfer to Nessler cylinder washing it with water. In the second Nessler cylinder, place 1 ml of dilute acetic acid and 2 ml of standard lead solution. Add to each cylinder, 10 ml of hydrogen sulphide solution and make up the volume with water to 50 ml. Mix, allow to stand for 10 minutes and then compare the colour produced in the two Nessler cylinders.

A-3.3.1 The limit prescribed in Table 1 shall be taken as not having been exceeded, if the intensity of colour produced in the test with the material is not greater than that produced in the second Nessler cylinder.

A-4. TEST FOR ARSENIC

A-4.1 Reagents

A-4.1.1 Concentrated Sulphuric Acid — See IS : 266 - 1977‡.

A-4.1.2 Concentrated Nitric Acid — See IS : 264 - 1976†.

A-4.2 Procedure

A-4.2.1 Preparation of Sample — Weigh 2·000 g of the sample in a Kjeldahl flask of 500-ml capacity. Add 5 to 10 ml of concentrated nitric acid followed by 4 ml of concentrated sulphuric acid. Heat cautiously. Add drop by drop more nitric acid, if required, from a pipette to speed up the oxidation of the sample. The total amount of nitric acid shall be noted for use in the control test. When oxidation is complete, the solution

*Specification for hydrochloric acid (second revision).

†Specification for nitric acid (second revision).

‡Specification for sulphuric acid (second revision).

is clear and faint yellow; at that stage, add 20 ml of water and again boil to fuming. Ensure removal of all nitric acid.

A-4.2.2 Carry out the test for arsenic with the solution prepared in **A-4.2.1** as given in IS : 2088 - 1983*. Compare the stain obtained with that produced with 0.002 g of arsenic trioxide.

A-5. ASSAY

A-5.1 Reagents

A-5.1.1 Standard Sodium Thiosulphate Solution — 0.1 N.

A-5.1.2 Standard Bromine Solution — 0.1 N.

A-5.1.3 Sodium Hydroxide Solution — 1 N.

A-5.1.4 Concentrated Hydrochloric Acid — See IS : 265 - 1976†.

A-5.1.5 Potassium Iodide Solution — 50 percent solution (*m/v*).

A-5.1.6 Starch Solution — freshly prepared (5 percent).

A-5.2 Procedure — Weigh accurately about 0.1 g of the sample in a 250 ml beaker, boil for 30 minutes with 50 ml of 1 N sodium hydroxide solution replacing the water lost by evaporation. Cool, transfer to a glass-stoppered flask and add immediately 50 ml of 0.1 N bromine and 10 ml of hydrochloric acid. Shake repeatedly during fifteen minutes, allow to stand for fifteen minutes, add 30 ml of solution of potassium iodide and titrate the liberated iodine with 0.1 N sodium thiosulphate solution using solution of starch as indicator. Repeat the experiment with same quantities of the same reagents in a similar manner omitting butyl *p*-hydroxybenzoate sample. The difference between the titration represents the amount of bromine required by the butyl *p*-hydroxybenzoate sample.

Each one ml of 0.1 N bromine is equivalent to 0.003 237 g of $C_{11}H_{14}O_3$.

A-6. DETERMINATION OF SULPHATED ASH

A-6.1 Reagent

A-6.1.1 Dilute Sulphuric Acid — approximately 4 N.

A-6.2 Procedure — Weigh accurately 1 to 2 g of sample in a tared crucible. Ignite until thoroughly charred, cool, and moisten with 1 ml of dilute sulphuric acid and cautiously ignite until the carbon is completely consumed. Conduct the ignition at a place protected from air currents and use as low

*Methods for determination of arsenic (*second revision*).

†Specification for hydrochloric acid (*second revision*).

a temperature as possible to effect the combustion of carbon. When carbon has completely disappeared, cool the crucible in a desiccator and weigh.

A-6.3 Calculation

$$\text{Sulphated ash, percent by mass} = \frac{100 \times m}{M}$$

where

m = mass in g of the residue obtained, and

M = mass in g of the sample taken for the test.

A-7. TEST FOR CHLORIDES

A-7.1 Apparatus

A-7.1.1 Nessler Cylinder — 50 ml capacity.

A-7.2 Reagents

A-7.2.1 Silver Nitrate Solution — 2 percent.

A-7.2.2 Dilute Nitric Acid — 4 N.

A-7.2.3 Hydrochloric Acid — 0·01 N, accurately standardized.

A-7.3 Procedure — Heat 2·000 g of sample with 100 ml of water, cool and add water to restore the original volume, and filter through cotton. Use the filtrate for test for chlorides and sulphates (A-9). Take 50 ml of the filtrate in a Nessler cylinder and add 1 ml of dilute nitric acid and 1 ml of silver nitrate solution. Carry out a control test in another Nessler cylinder using 1·0 ml of standard hydrochloric acid and the same quantities of other reagents as used with the sample. Allow the cylinder to stand for 5 minutes protected from direct sunlight and compare the turbidity.

A-7.3.1 The sample shall be taken to have passed the test if the turbidity produced with the sample is not greater than that produced in the control test.

A-8. TEST FOR SULPHATES

A-8.1 Reagents

A-8.1.1 Dilute Hydrochloric Acid — 4 N.

A-8.1.2 Barium Chloride Solution — 10 percent.

A-8.2 Procedure — Take a 10 ml aliquot of the filtrate preserved in A-7.3 in a Nessler cylinder, add a few drops of dilute hydrochloric acid and a few drops of barium chloride solution. Mix and allow to stand for 15 minutes.

A-8.2.1 The sample shall be taken to have passed the test if the solution remains clear when viewed against a black background.

A-9. REACTION

A-9.1 Procedure — Heat 0.75 g of sample in 15 ml of water to 80°C for one minute. Cool and filter. The filtrate shall be neutral or slightly acidic to solution of litmus. Further, take 10 ml of filtrate, add 0.2 ml of 0.1 N sodium hydroxide and 2 drops of methyl red solution. The sample shall be taken to have passed the test, if the solution is yellow in colour.

A P P E N D I X B

(Clause 4.1)

SAMPLING OF BUTYL *p*-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

B-1. GENERAL REQUIREMENTS OF SAMPLING

B-1.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observed.

B-1.1 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-1.2 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-1.3 The sample shall be placed in clean, dry, airtight glass or other suitable containers.

B-1.4 Each sample container shall be sealed airtight with a suitable stopper after filling, and marked with full details of sampling, date of sampling, and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot — All the containers in a single consignment of the material drawn from the same batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot separately for ascertaining conformity of the material to the requirements of this specification.

B-2.2 The number of containers (n) to be chosen from the lot shall depend on the size of the lot (N) and shall be as given below:

<i>Lot Size</i>	<i>No. of Containers to be Selected</i>
(N)	(n)
Up to 50	3
51 ,, 200	4
201 ,, 400	5
401 ,, 650	6
651 ,, 1 000	7
1 001 and above	8

B-2.3 The containers to be selected for sampling shall be chosen at random. In order to ensure randomness of selection, random number tables shall be used. For guidance and use of random number tables, IS : 4905 - 1968* may be referred. In the absence of random number tables, the following procedure may be adopted:

'Starting from any container in the lot, count them as 1, 2, 3, , up to r and so on in one order, where r is the integral part of N/n , N being the lot size and n the sample size. Every r th container thus counted shall be withdrawn from the lot so as to constitute the required sample size.'

B-3. TEST SAMPLES AND REFEREE SAMPLE

B-3.1 Preparation of Test Samples

B-3.1.1 Draw with an appropriate sampling instrument, a small portion of the material from different parts of each container selected (see B-2.2). The total quantity of the material drawn from each container shall be

*Methods for random sampling.

sufficient to conduct the tests for all the characteristics given under 2 and shall be not less than 250 g.

B-3.1.2 Thoroughly mix all portions of the material drawn from the same container. Out of these portions, equal quantity shall be taken from each selected container and shall be well mixed up together so as to form a composite sample weighing not less than 500 g. The composite sample shall be divided into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.1.3 The remaining portion of the material from each container (after the quantity needed for the formation of composite sample has been taken) shall be divided into three equal parts, each part weighing not less than 100 g. These parts shall be immediately transferred to thoroughly dried bottles which shall then be sealed airtight with stoppers and labelled with all the particulars of sampling. The material in each such sealed bottle shall constitute an individual test sample. These individual samples shall be separated into three identical sets of samples in such a way that each set has an individual test sample representing each container selected. One of these three sets shall be sent to the purchaser, another to the supplier and the third shall be used for the referee.

B-3.2 Referee Sample — The referee sample shall consist of composite sample (B-3.1.2) and a set of individual samples (B-3.1.3) marked for this purpose and shall bear the seals of the purchaser and the supplier. These shall be kept at a place agreed to between the purchaser and the supplier, and shall be used in case of dispute between the two.

B-4. NUMBER OF TESTS

B-4.1 Test for assay shall be conducted on each of the individual samples.

B-4.2 Tests for the remaining characteristics given in 2 and Table 1 shall be conducted on the composite sample (B-3.1.2).

B-5. CRITERIA FOR CONFORMITY

B-5.1 For Individual Samples -- The mean \bar{X} and range R for the test results shall be calculated (range being the difference between the maximum and the minimum test results).

B-5.1.1 The lot shall be declared to have satisfied the requirement for assay if the value of the expression ($\bar{X} - 0.6 R$) is equal to or greater than 99.0.

B-5.2 For Composite Sample — The test results on the composite sample shall meet the corresponding requirements specified in 2 and Table 1.

B-5.3 A lot shall be declared as conforming to this specification if it satisfies the requirements for each of the characteristics listed under 2 and in Table 1. If the requirements for any of the characteristics are not met, the lot shall be declared to have not satisfied the requirements of the specification.

(Continued from page 2)

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AMENDMENT NO. 1 MAY 2002
TO
**IS 6334 : 1987 SPECIFICATION FOR BUTYL
p-HYDROXYBENZOATE FOR COSMETIC INDUSTRY**
(*Second Revision*)

[*Page 4, Table 1, Sl No.(ii), col 3*] — Substitute '2.0' for '5'.

[*Page 4, Table 1, Sl No.(iii), col 3*] — Substitute '2' for '1'.

(*Page 7, clause A-3.3, line 1*) — Substitute '4.000 g' for '1.000 g'.

(*Page 7, clause A-4.2.1, line 1*) — Substitute '2.000 g' for '1.000 g'.

(*Page 8, clause A-5 to A-5.2*) — Substitute the following for the existing:

A-5 ASSAY

A-5.1 Reagents

A-5.1.1 Standard Sodium Hydroxide Solution — 1 N.

A-5.1.2 Standard Sulphuric Acid — 1N.

A-5.1.3 Bromothymol Blue Indicator Solution

A-5.1.4 Phosphate Buffer

A-5.2 Procedure

Transfer to a flask equipped for refluxing under a water-cooled condenser about 2 g of butyl paraben, accurately weighed, add 40.0 ml of 1 N Standard sodium hydroxide solution, and rinse the sides of the flask with water. Reflux for 1 hour and cool. Add 5 drops of bromothymol blue indicator solution, and titrate the excess sodium hydroxide with 1N standard sulfuric acid to a pH of 6.6 by matching the colour of pH 6.6 phosphate buffer containing the same proportion of indicator. Perform a blank determination. Each ml of 1 N sodium hydroxide is equivalent to 194.15 mg of . C₁₁H₁₄O₃.

AMENDMENT NO. 2 JULY 2009
TO
IS 6334 : 1987 SPECIFICATION FOR BUTYL
p-HYDROXYBENZOATE FOR COSMETIC INDUSTRY

(*Second Revision*)

(Page 4, Table 1, Sl No. (ii), col 3 (see also Amendment No. 1) —
Substitute '20' for '2.0'.

(PCD 19)

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